Fiscal and Structural Subgroup—Meeting Three Minutes
October 15, 2020
1:00 PM
Virtual Meeting via Webex
https://www.youtube.com/watch?v=pOErYF8Y4Ck

Meeting Attendees:
Secretary of Public Safety Brian Moran
Asst. Sec. of Health and Human Resources Catie Finley, on behalf of Secretary Daniel Carey
Jenn Michelle Pedini (Virginia NORML)
Commissioner Jewel Bronaugh (VDACS)
Kristin Collins (Tax Department)
Ngiste Abebe (Columbia Care)
Nate Green (Virginia Association of Commonwealth's Attorneys)
Dr. David Brown (Department of Health Professions, on behalf of Caroline Juran)
Kristen Collins (Tax Department), on behalf of Commissioner Craig Burns
Mike MacKenzie (VCU Wilder School)
Michael Carter (VSU Small Farm Outreach Program and farmer)
Colby Ferguson (DMV)
Dr. Sam Caughron (Charlottesville Family Wellness Practice)
Travis Hill (ABC)
Joe Mayer (Tax Department)
Charles Green (VDACS)
David Barron (DFS)
Richard Boyd (VSP)
John Welch (VSP)
Deputy Secretary of Public Safety and Homeland Security Nicky Zamostny

Staff:
Deputy Secretary of Agriculture and Forestry Brad Copenhaver
Jacquelyn Katuin, Policy Advisor to Secretary Moran

Commissioner Bronaugh began the meeting at 1:05 PM.

Approval of August 17, 2020 Minutes

- Commissioner Bronaugh called for a vote to approve the minutes of the subgroup's last meeting on September 11, 2020.

Roll Call Vote: 11 yes, 0 no

- Unanimous in favor of approval of minutes

Guest Speaker: Caroline Juran, Executive Director, Virginia Board of Pharmacy (BOP)

The BOP oversees the Pharmaceutical Processor Program (medical marijuana program). The BOP is one of 13 health regulatory boards in the Department of Health Professions (DHP). Their

mission is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public. DHP licenses and regulates licensees across 60 professions.

DHP is a non-general fund agency and must cover its expenses via licensing fees. Monetary penalties must be transferred to the state literary fund within the Department of Education.

The law requires 8 pharmacists and 2 citizen members to be appointed by the Governor to the Board. They currently have one vacancy of a citizen member.

In 2015, the General Assembly passed a law that provided an affirmative defense for patients to possess these oils but did not include a legal way for these oils to be produced in Virginia. In 2016, they passed a law authorizing these oils to be produced—5 processors (1 in each health district) to dispense CBD and THC-A oil to patients who have a prescription for intractable epilepsy. This had to be reenacted in 2017 to become law. Emergency regulations became effective in August 2017. In 2018, the law was expanded to include any diagnosed condition or disease. In 2019, the law was expanded again to include nurse practitioners and physicians' assistants to issue written certificates for obtaining these oils. This law also created authority for BOP to register a "registered agent" who may be designated by a patient to receive CBD or THC-A oil on his/her behalf (e.g. for a bedridden patient). The bill also created an ability for processors to wholesale distribute oils among themselves.

In 2020, the bill removed the affirmative defense, replaced "cannabidiol" and "THC-A oil" terms with "cannabis oil", removed 5% THC cap, but retains THC cap/dose, authorized use of telemedicine consistent with federal requirements for Rx drugs (patient cannot be at home—must be in a DEA registered facility), allowed persons temporarily residing in Virginia to obtain patient registration, and authorized up to 5 cannabis dispensing facility permits per health service area (HSA), which could take the number of sites up to 30 potentially.

The definition of cannabis oil is in statute. Cannabis oil" means: any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by processor, or a dilution of the resin of the Cannabis plant that contains at least 5 mg of CBD or THC-A and no more than 10 mg of delta-9-tetrahydrocannabinol per dose. Processors can now also obtain hemp-derived oil from VDACS registered hemp processors.

A pharmaceutical processor is a facility permitted by Board of Pharmacy. It must be a vertical operation that includes: indoor cultivation of Cannabis plants; production of cannabis oil; and dispensing of oils by pharmacist to registered patients. The permitting process was divided into 3 phases: initial application; conditional approval; issuance of the permit. At the conclusion of the competitive process, the board issued conditional approval to 5 applicants—they then had 1 year to build their facilities and become operational. Recently the board rescinded 1 of these approvals. 3 facilities are permitted and are in different stages of becoming operational, and the 4th facility is close to being permitted. Just recently, the first facility started dispensing products. During the initial application stage, each applicant paid a $10K application fee; the 5 awarded conditional approval also paid a $60K permit fee; and those permitted must pay an annual renewal fee of $10K.

Each processor operates under supervision of a pharmacist. Board quarterly inspections of the facilities are required. Oils independently laboratory tested prior to dispensing. Lab results are available upon request to patients, parents/guardians, and practitioners, and products must be registered by BOP.

(See Slide 13 for a list of current pharmaceutical processors).

They are required to perform lab testing of the products. This testing includes microbiological, mycotoxins, heavy metals, pesticide chemical residue, residual solvent, active ingredient analysis (CBD, CBDA, THC, THC-A). They must include a 6 month expiration date, unless a different date is based on a stability test.

Many things have taken a little longer than expected. It is hard to predict everything. During the RFA in 2018, we had to give the evaluation committee a little longer than expected to review applications (voluminous and large number of applicants). Each reviewer had to review 82 banker boxes worth of information, and we extended the period from 30 days to 60 days. We gave the processors 12 months to construct their facilities and become operational (every one needed a slightly longer period of time). We were told it would take approximately 3-6 months to cultivate and produce products. But it's October now, and our first processor has just started dispensing or is about to start dispensing any day now. We started issuing patient registrations in 2018 and have had to extend their 12 month expirations twice because we didn't think it was appropriate to require a renewal payment with no product available. So, many things in this process have taken a little bit longer than anticipated. Having said that, this is a large undertaking and a very fluid subject, and I think everyone has done a pretty impressive job to get this program operational.

Several vape formulations with high THC/THC-A concentrations are available now. Also, we have a low concentration THC/CBD oil for oral administration, a THC/THC-A nasal spray, and a low THC/CBD chewable product.

This is a tightly regulated medical programs, and there are requirements for what a practitioner must do: conduct an assessment and evaluation of the patient to develop a treatment plan; obtain patient's medical history, prescription history, current medical condition; diagnose the patient; be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient; explain proper administration, potential risks and benefits, prior to issuing the written certification; be available or ensure that another practitioner is available to provide follow-up care and treatment to determine efficacy of CBD oil or THC---A oil for treating the diagnosed condition or disease; access to the Virginia Prescription Monitoring Program; practitioner shall not delegate responsibility of diagnosing a patient or determining whether a patient should be issued a certification; cannot issue more than 600 certifications at any given time—can petition Boards of Pharmacy & Medicine for increase.

There are also several prohibited practices that a practitioner cannot do: directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia; offer a discount or any other thing of value to a qualifying patient, parent or guardian based on the patient's agreement or decision to use a

particular pharmaceutical processor or cannabidiol oil or THC-A oil product; examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil is dispensed or produced; a practitioner, and such practitioner's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase or use of cannabis oil; a practitioner shall not issue a certification for himself or for family members, employees or co-workers; a practitioner shall not provide product samples containing cannabis oil other than those approved by the United States Food and Drug Administration.

We have a fairly straightforward registration application process online for all parties. We ask registrants to demonstrate that they are a resident or temporary resident of the Commonwealth and provide a copy of their written certification. There is a $50 application fee initially and annually for patients and practitioners, and for parents/guardians and registered agents this is $25.

Snapshot of registered patients as of October 9: Registered Practitioners: 537; Registered Patients: 5,920; Registered Parents/Guardians: 68; Registered Agents: 9. We have seen a steady stream of 200-250 applications for patients per week. So, if this program were to expand to include flower, we will have to give serious consideration to procuring a more robust software platform designed to register cannabis patients. Currently using our licensing database which is not ideal. It's somewhat manual and there is no continuity between the steps in the patient registration process: prescriber issuing a written certification, patient applying for registration, and patient obtaining oil from the processor. Other states have an electronic mechanism that ties all these steps together.

Dr. Bronaugh: Thank you for that comprehensive overview. Any questions for Caroline?

Sec. Moran: Yesterday we had a meeting about health impacts of marijuana, and we were looking forward to your presentation for lessons learned about setting up this program. Could you tell us more about your experience and what we could glean as we potentially move into the recreational world?

Ms. Juran: From an operational standpoint, expect things to take longer than you originally think. But some of the nuances, obstacles, and challenges we have already worked through. There will probably be additional issues related to the volume of items in an adult use program—DHP likely could not handle this, but there could be a role for us. Tax revenue will also be a challenge that we are not currently dealing with in the medical program. From a health effects standpoint, there is scant research about cannabis use in a medical setting. We know there are drug/drug interactions for some products. This is all overseen by pharmacists and practitioners.

Sec. Moran: Could you comment on the experience of vertical integration and how that has worked?

Ms. Juran: It is a lot of activity to occur under one roof, and it takes a lot of money to stand up one of these processors. It puts applicants that have resources in a position of being a stronger

candidate. Most processors operate in multiple states. We see a trend in other states where they are trying to provide economic opportunity by spreading out those responsibilities. Our model is working fine, but it is expensive.

Asst. Sec. Finley: Could you give us a high level summary of how the types of products that are allowed works, especially given that we do not allow flower in this program? And could you also talk about the resource needs (FTEs)?

Ms. Juran: Our program is fairly expansive even though we do not allow the sale of flower. The cannabis oil definition is broad, and there is no THC cap. And practitioners can prescribe for any condition they see as necessary. So we are getting applications for high THC vaped products (40% THC—combination 27% THC-A). And the oral products seem to have lower concentrations. There are probably some patients that would prefer flower. But minus flower, we have a very expansive program in place. A potential workload increase would be associated with registering additional patients who are interested in purchasing flower if that is allowed. We do not have that manpower right now. We have about 6,000 patients, and some states have 50,000-70,000 patients.

Dep. Sec. Copenhaver: Can you explain more about the delays that you mentioned? What are the pitfalls to getting up and running?

Ms. Juran: The current processors could probably give a more detailed response, but some reasons were getting local permits and other permissions at the local level, construction and weather, getting materials, and maybe some financial aspects. For the one location where we rescinded approval, there just was not enough action at the site—there was no building yet at that site. That company also experienced a change in ownership, and that is something that seems to happen frequently in the industry.

Mr. Carter: What is the estimated cost of setting up one of these vertical operations?

Ms. Juran: We have heard it is in the millions of dollars, but I cannot provide specifics.

Ms. Abebe: It is typically a multimillion dollar investment—anywhere from 2-5 million to 12-15 million. Typically this model is generally used early in the industry to prevent diversion of products, and it is generally accepted now that vertical integration should not be required.

Dr. Caughron: Do you have any thoughts about personal cultivation?

Ms. Juran: That would really be up to the General Assembly. There may potentially be an impact to our program if that was allowed and our program was allowed to sell flower.

Dep. Sec. Copenhaver: If we have additional questions, we can follow up with Caroline.

Guest Speaker, Travis Hill, Virginia ABC

ABC is an organization that regulates a controlled substance and the last substance that was one illegal. Since 2018, ABC has been an independent authority from the Commonwealth, but we work closely with the Secretary of Public Safety—this communication is important—budget requests and legislative issues. We have a part time board of 5 members appointed by the governor, and there is a requirement that they have a business requirement. CEO must also have a business background and is appointed by the governor. The board serves 5 year staggered terms, and can serve up to 2 terms.

The responsibilities of ABC: retailing distilled spirits, and regulating alcoholic beverages in Virginia. We are a "control state" and sell spirits both wholesale and retail. We operate 389 retail stores. Out of that, we generate about $220 million in profits for the Commonwealth, and with taxes, we transfer over $500 million to the Commonwealth each year. Some of that goes to DBHDS for treatment program and some goes to other set-asides. But the majority goes into the General Fund.

We regulate manufacturers, wholesalers, and retailers, and this is known as the "three tier system". Vertical integration is not allowed for alcohol in Virginia. Over time, those lives have been blurred a bit—such as being able to consume on site at a brewery. We license these various entities, which we do with a bureau of law enforcement—over 100 staffer members (mid-80s of fully sworn agents). We also have a civilian staff of licensing and records management and tax collection.

Field agents are responsible for visits to licensed establishments. They work with them to ensure they are in compliance, and they are involved from the very beginning of the licensing process. We also continue to enforce unlicensed stills and untaxed liquor, but this is a smaller part of the responsibilities. In Virginia, in order to have a still, you need to have a license. You cannot make distilled spirits without a license, but you can do so for beer and wine as long as it does not enter the chain of commerce.

We also have compliance agents that are responsible for the wholesale and manufacturing tier. Agents work with breweries, wineries, and distilleries to ensure they are complying with all the laws for production and entering into the chain of commerce.

We also have a hearings division, and we hold 500 hearings a year on license application and license violation actions, such as underage sale or illegal behavior in business practices. All decisions are appealable to the circuit court.

We also have some tobacco enforcement capabilities. And this year, we are doing a little bit in the realm of regulating gaming devices for "games of skill". We had to stand this up pretty quickly this year.

We have an effort to move our licensing system all online—make engagement with the regulated community more seamless.

We generate a forecast based on our profits and we fund our own operations. This is included in the Governor's introduced budget and is incorporated into the budget by the General Assembly. We also have Chief Tom Kirby with us today.

Chief Kirby: I am more than happy to answer questions. In the enforcement division, we have just under 200 staff members that do all of that work. We maintain about 18,000 retail licenses in Virginia. We process about 2,000 applications each year for new licenses. For games of skill, we took in about 87 distributers, representing about 10,000 games. We are in the process now of continuing to monitor that activity—we track movement of the machines and collection of the taxes associated with them.

Group Discussion

Dr. Bronuagh: We need to get to a point where we are making some recommendations. Some folks wanted to know a status report of the JLARC report. We also want to consider questions like: who should serve as the primary regulator, where should the leadership be housed, what should the tax structure be, are there any public health priorities we would like to focus on for revenues, and what licensing models would we like to consider?

Mr. MacKenzie: We are working with Tax and VEDP to do some economic modeling. We met with morning. We are not trying to duplicate the work of JLARC. We are talking about what the final product will look like, and our models will likely be comparative with other states.

Dep. Sec. Copenhaver: We did have a meeting with JLARC to discuss. There is only so much they are able to share with us, but we are confident our reports will be complimentary. We are confident that we are on the right track with our topics. Also, we just need to remember that our processes are very different from JLARC's (more closed vs. more open). And JLARC has had many more resources to do their economic analysis.

Dr. Bronaugh: Now, let's open the discussion of the different topics this group needs to discuss and see where there are areas of consensus. One area of discussion is about who can serve as the primary regulator. Other states' programs are all over the board. Would this be under one agency or multiple agencies? We have learned that it is a best practice not to spread responsibilities too much.

Mx. Pedini: This is a conversation that has been ongoing. We currently have BOP regulating medical cannabis, and we have VDACS regulating hemp, including products for human consumption. This is already a bit cumbersome, and we need a regulatory agency that can create a cannabis ecosystem. We need something that can house all three (including adult use) and oversee consumer safety.

Dep. Sec. Copenhaver: Would that be something that would be an umbrella and cover different agencies, or would be more like a brand new agency where everything goes?

Mx. Pedini: That is really the big question. We can't overlook that BOP is involved in the process and as long as a pharmacist is involved, BOP will be as well to some extent. And we

have industrial hemp at VDACS. Do we want to shift all of that to a new agency? Or create an umbrella of sort?

Ms. Abebe: There are some challenges that BOP faces due to their revenue situation. We should strive for a more synchronized regulatory environment. For example, a CBD shop can advertise, and this has led to cartoon cannabis leaves as logos. Being able to have some consistency so the average consumer understands what they are seeing is important. Where do folks currently inside government see a structure like this fitting in?

Dep. Sec. Copenhaver: We don't want to have to legislate pathways for agencies to connect. It is difficult to think through how an umbrella would work that leaves autonomy for other agencies. Also, keep in mind that VDACS is running a hemp program that is federally compliant, which is different. If we have to thread them all together, would we forget to draw those connections? Would it be easier to just put everything in one agency?

Mx. Pedini: One solution about the hemp issue could be to bifurcate out industrial hemp and those hemp derived products that are intended for human consumption. Also remember that the medical licensees are also likely to be licenses in adult use as well.

Mr. Hill: If you have legalized marijuana for adult use, where do you draw the line between recreational adult use and medical? What we heard from Massachusetts is that we need to take the time to get it right and also don't forget about how much money will be needed to set this up.

Mx. Pedini: We have existing regulators that can fill in the gap from the time the state legalizes marijuana to when retail sales begin. If we do not provide a solution with our existing regulators, we could encourage an illicit market. We started our medical program with no state funding. Even if we have adult use, there is definitely a need to maintain a medical program, which serves pediatric patients and others who need a healthcare experience. We are not rushing into this as a state—we have taken 5 years to get to this point with our medical program. No state gets it right the first time.

Ms. Abebe: Cannabis is a plant that can be used for industrial purposes, medical purposes, and adult use purposes, and we don't really have a good model in our government for how to deal with all three of those things at one time. We have data that show that in more mature markets, about 2/3 of the folks coming into an adult use dispensary are coming in for health and wellness reasons. This is similar to going to a pharmacy and getting your prescription and also getting over the counter products. Cannabis is on a similar kind of spectrum. It is different though because it can also be used for a recreational purpose. We know how to regulate this though and encourage responsible consumption.

Dr. Bronaugh: Shouldn't this report at least recommend that we include some appropriated funding to start a program—it is very hard to start a program with just existing resources.

Mx. Pedini: Funding would be helpful.

Ms. Juran: I see DHP aligned on the medical side, but not really on the adult use side. What role do you envision us have in the adult use program?

Mx. Pedini: The board's involvement would probably limited to however a pharmacist is involved in the process. There may be an early time where we need help with early sales too.

Ms. Juran: Would it then even be appropriate to have a pharmacist involved in the adult use program?

Mx. Pedini: Probably not, but we could still have both adult use and medical operators.

Ms. Juran: If this current program under BOP oversight is envisioned to transition to adult use, resources would be a concern. We have heard examples of when states have legalized, most people switch out of the medical program and over to adult use.

Ms. Abebe: There are differences between the western and eastern states who legalized. The more recent, eastern states have maintained a robust medical program. The Illinois used fees on the existing medical providers to help with the transition to the adult use program.

Dep. Sec. Zamostny: Can you explain more about how the new telemedicine allowance works? Is this due specifically with this issue or the ongoing telemedicine issue that has been going on for a long time in Virginia?

Mx. Pedini: This is specific to the medical cannabis issue.

Dr. Caughron: The restrictions on telemedicine for dealing with cannabis are higher than in general.

Dep. Sec. Zamostny: Is that based on just the type of substance this is?

Dr. Caughron: The requirement will likely become antiquated in the future.

Ms. Juran: The requirement currently in place is consistent with federal requirement that is in place for prescribing Schedule 2-5 substance, and the idea was that we wanted to mirror that requirement because marijuana seems to align more with those.

Dr. Caughron: That requirement may have changed recently.

Ms. Juran: There may be some waivers in place because of the pandemic.

Dr. Bronaugh: We need to consider what we think the license and market structure would look like. What do we feel would be the most beneficial for creating economic opportunity in the Commonwealth?

Ms. Juran: There are some valid points made about creating opportunities by separating out parts of the supply chain and not requiring vertical integration.

Mx. Pedini: We need to focus on creating opportunity and lowering barriers to entry into this industry. We need a structure that allows for this opportunity but does not complicate things for the consumer. Some states have a separate distributor license, and that can create additional costs for the consumer at the end of the day. Some states allow both vertical and tiered systems to exist side by side. And we also need to think about other categories, such as delivery and hospitality.

Ms. Abebe: There is no way to have an equitable program if you require vertical integration, but the medical processors are already up and running and have had to comply with certain regulations. So vertical integration should be allowed but not required. On the hospitality front, we need to think about social consumption as well. Cigar lounges are a good example of how to do this. Also, if you live in federally-subsidized housing, you would not be allowed to legally consume something that you bought as a medication, so that is another reason why social consumption spaces are important. We also need to figure out the right amount of employee protections for folks who are consuming. There is good model language in other states that maintains federal compliance but also outlines employer rights.

Mr. Carter: A license for cultivators should be similar to what is required for hemp now. And it would be preferable to have the retailers collect the tax rather than at the farm level.

Ms. Abebe: For those selling both adult use and medical cannabis, the later the taxation point is, the easier it is to manage supply. It also simplifies the accounting for industry participants.

Mr. Hill: It probably needs to be a broader set of licenses rather than very specific. This will allow businesses to be creative and also create efficiencies. The taxation structure is going to play a large role in how markets form.

Public Comment

Paul McLean, Virginia Minority Cannabis Coalition: Has the state been involved at all in the choice of strains that the medical processors can produce? Has there been any social equity components within the medical processors?

> Ms. Abebe: There is no mandate from the state regarding which strains we grow. There is no social equity component to the existing program, but Columbia Care has its own initiatives at the company level.
>
> Ms. Juran: The law does not specify types of strains. And the law does not contain any requirements with regard to social equity.

The group also discussed having one additional meeting to discuss items where consensus has not yet been reached.

Commissioner Bronaugh adjourned the meeting at 3:10 PM.

Chat Box During Meeting

from Sarah Blahovec to all panelists: 1:49 PM
Hello, my name is Sarah Blahovec. My question: what, if anything, is being done to ensure ADA compliance of both the physical locations of the dispensaries and web accessibility of dispensary websites (WCAG 2.0 AA rating or higher?)
from Sarah Blahovec to all panelists: 1:50 PM
Thank you!
from Sara Payne to all panelists: 2:21 PM
The hemp program is only partially federally legal - it depends on which federal agency you ask.
from Sara Payne to all panelists: 2:22 PM
No hemp CBD products intended for human or animal consumption are "legal" if you ask FDA.
from Sara Payne to all panelists: 2:45 PM
Often the medical program decline is reflective of how difficult it is for patients to navigate the medical program involved (and as Ngiste mentioned, product access and availability). Product cost is another issue that drives medical program decline, and declines are often exacerbated when botanical (less expensive) products are not available in the medical program.

Virginia Department of Health Professions

Virginia Board of Pharmacy

Fiscal and Structural Subgroup
Marijuana Legalization

October 15, 2020

Caroline D. Juran, RPh
Executive Director, Board of Pharmacy

Virginia Department of Health Professions

Department of Health Profession

- Mission: To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.
- 13 health regulatory boards, Board of Health Professions, Prescription Monitoring Program, Health Practitioners' Monitoring program, Healthcare Workforce Data Center
- Regulates healthcare practitioners over 60 professions

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Virginia Department of Health Professions

Department of Health Profession

- Non-General Fund agency
- Must cover expenses through licensing fees
- Monetary penalties must be transferred to State Literary Fund within DOE

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Virginia Department of Health Professions

Board Members

Kristopher S. Ratliff, *Chairman*	Ryan K. Logan
Cheryl H. Nelson, *Vice Chairman*	William Lee
Glenn Bolyard	Sarah Melton
vacant, *Citizen*	Patricia Richards-Spruill
James L. Jenkins, Jr., *Citizen*	Dale St.Clair

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Virginia Department of Health Professions

Pharmaceutical Processor Laws

2015

- Authorized physician to issue written certification providing affirmative defense for possessing CBD oil and THC-A oil

2016

- Directed BOP to oversee CBD oil and THC-A oil production and dispensing by up to 5 pharmaceutical processors for treatment of intractable epilepsy

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Virginia Department of Health Professions

Pharmaceutical Processor Laws

2017

- Reenacted legislation, as required by 2016 bill.
- August 2017: Emergency regulations became effective; establish health, safety and security requirements for processors

2018

- Expanded program to allow physician to issue certification for the use of CBD oil or THC-A oil for the treatment of any diagnosed condition or disease

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Virginia Department of Health Professions

Pharmaceutical Processor Laws

2019

- Expanded authority to physician assistants and nurse practitioners to issue written certifications
- Created authority for BOP to register a "registered agent" who may be designated by a patient to receive CBD or THC-A oil on his/her behalf
- Allows processors to wholesale distribute oil products between processors

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Virginia Department of Health Professions

Pharmaceutical Processor Laws

2020

- Removes affirmative defense
- Replaces "cannabidiol" and "THC-A oil" terms with "cannabis oil"; removes 5% THC cap, but retains THC cap/dose
- Authorizes use of telemedicine consistent with federal requirements for Rx drugs
- Allows persons temporarily residing in Virginia to obtain patient registration
- Authorizes up to 5 cannabis dispensing facility permits per HSA

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Virginia Department of Health Professions

§54.1-3408.3

- "Cannabis oil" means:
  - any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by processor, or a dilution of the resin of the Cannabis plant
    - that contains at least 5 mg of CBD or THC-A and
    - no more than 10 mg of delta-9-tetrahydrocannabinol per dose.

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Virginia Department of Health Professions

Pharmaceutical Processor

- Facility permitted by Board of Pharmacy
- Vertical operation:
  - Indoor cultivation of Cannabis plants;
  - Production of cannabis oil;
  - Dispensing of oils by pharmacist to registered patients

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Virginia Department of Health Professions

Pharmaceutical Processor, cont.

- Operates under supervision of a pharmacist.
- Board quarterly inspections required.
- Oils independently laboratory tested prior to dispensing.
- Lab results available upon request to patients, parents/guardians, practitioners.
- Products must be registered by BOP

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Virginia Department of Health Professions

Pharmaceutical Processors

- HSA I = vacant
- HSA II = Dalitso LLC, Manassas
- HSA III = Dharma Pharmaceuticals, Bristol
- HSA IV = Green Leaf Medical of Virginia LLC, Richmond
- HSA V = Columbia Care Eastern Virginia LLC, Portsmouth

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Virginia Department of Health Professions

Lab Testing of Oil Products

- Microbiological
- Mycotoxin
- Heavy metals
- Pesticide chemical residue
- Residual solvent
- Active ingredient analysis (CBD, CBDA, THC, THC-A)
- Expiration date based on stability test

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Virginia Department of Health Professions

Availability of Oil Products

- Approximately 3-6 months to cultivate and produce oils
- Processor anticipates availability of oils in August
- Patients may access any of the pharmaceutical processor sites

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Virginia Department of Health Professions

Practitioner Requirements

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Virginia Department of Health Professions

Practitioner Requirements 18VAC110-60-30

- Conduct an assessment and evaluation of the patient to develop a treatment plan; obtain patient's medical history, prescription history, current medical condition
- Diagnose the patient;
- Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

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Virginia Department of Health Professions

Practitioner Requirements, cont.

- Explain proper administration, potential risks and benefits, prior to issuing the written certification;
- Be available or ensure that another practitioner is available to provide follow-up care and treatment to determine efficacy of CBD oil or THC-A oil for treating the diagnosed condition or disease;
- Access to the Virginia Prescription Monitoring Program;

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Virginia Department of Health Professions

Practitioner Requirements, cont.

- Practitioner shall not delegate responsibility of diagnosing a patient or determining whether a patient should be issued a certification.
- Cannot issue more than 600 certifications at any given time. Can petition Boards of Pharmacy & Medicine for increase.

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Virginia Department of Health Professions

Practitioner Prohibitions

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Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia;
- Offer a discount or any other thing of value to a qualifying patient, parent or guardian based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabidiol oil or THC-A oil product;

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Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil is dispensed or produced;
- A practitioner, and such practitioner's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase or use of cannabis oil

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Virginia Department of Health Professions

Prohibited Practices of Practitioner, 18VAC110-60-40

- A practitioner shall not issue a certification for himself or for family members, employees or co-workers
- A practitioner shall not provide product samples containing cannabis oil other than those approved by the United States Food and Drug Administration.

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Virginia Department of Health Professions

Board Registrations

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Virginia Department of Health Professions

Registrations

- Online applications
- Patient & Practitioner = $50 initial and annual fee
- Parent/Legal Guardian = $25 initial and annual fee
- Registered Agent = $25 initial and annual fee

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Virginia Department of Health Professions

Registrations as of 10/9/2020

- Registered Practitioners: 537
- Registered Patients: 5,920
- Registered Parents/Guardians: 68
- Registered Agents: 9

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Virginia Department of Health Professions

Contact Information

Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
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Henrico, VA 23233
(804) 367-4456

cbd@dhp.virginia.gov – CBD, pharmaceutical processor – related questions
pharmbd@dhp.virginia.gov - General board questions

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